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Pu Zhou

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EXAMINER

SHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/026,517	Applicant(s) ZHOU, PU	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-9,11,12 and 29-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,7,8 and 30-32 is/are allowed.
- 6) ☒ Claim(s) 9,11,12,29,33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 11, 12, 29, 33, 34, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemmer et al. (US Patent No. 5,531,685) in view of Bolduc et al. (US Patent No. 6,622,367). Hemmer discloses the device substantially as claimed including a medical catheter system (Figs. 1-6) comprising: a first steerable guide catheter (Fig. 1) having an entrance orifice (near 14), an exit orifice (near 16) and a first wall (12) surrounding a channel linking the entrance orifice and the exit orifice (Fig. 4), the first wall having a bendable memory portion (18), wherein the first wall contains a first layer, a second layer and a third layer, each layer having a different hardness (depending on how one interprets the layers, the first-third layers could be 110, 114 and

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112 in Fig. 4, with 110 being the softest and 112 being the hardest (col. 8, lines 35-57 disclose that the layers increase in hardness from 110-112). The first-Third layers could also be interpreted as 112, 116 and 64 in Fig. 4, with each being a different hardness. Col. 8, lines 50-52 disclose that 112 is made from a plastic which has a different hardness than 116 which col. 8, line 45 discloses is made from stainless steel, and that has a different hardness than 64, which col. 8, lines 59 and 66 disclose 64 as being made from copper for example. The website {http://www.gordonengland.co.uk/hardness/hardness_conv_chart.htm} discloses a chart that shows that steel and copper each have different hardness (steel is labeled D and copper is labeled B and the labeled chart for the metals is at the bottom of the page of website {<http://www.gordonengland.co.uk/hardness/rockwell.htm>}. Therefore it can be said that Hemmer teaches three layers within a first wall, and each having a different hardness), wherein the bendable memory portion has a first straight configuration during insertion and a second curved configuration upon activation (col. 6, lines 35-52).

Hemmer, however, does not disclose that the catheter has flushing orifices or a flushing line positioned about the first catheter. Bolduc, however, discloses a catheter system (Fig. 19) which has a guide catheter (500; col. 18, lines 41-45 disclose that catheter 500 may also be catheter 400 in Fig. 12, which is what the examiner is now interpreting to be the guide catheter) which has flushing orifices (Fig. 12, 408 and 410). The catheter system in Fig. 19 further discloses a flushing line positioned about the first catheter (the examiner is interpreting sheath 60 to be the flushing line, as col. 19, lines 27-31 disclose that 60 may be used to infuse fluids from the fluid system 715 which

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would then flow around catheter 500/400 and therefore be in fluid communication with the flushing orifices). Bolduc further discloses that the catheter 400/500 may be manufactured in any suitable conventional manner such as that described in columns 22-25. In particular, col. 24, lines 48-51 and 61-66 disclose that the catheter is made with multiple regions of varying hardness, to allow the catheter to have the hardness, strength and flexibility needed be a guide catheter and col. 24, lines 37-39 disclose that the catheter may be made with a shape memory alloy (curve memory portion).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Flynn's catheter to include flushing orifices and a flushing line positioned about it, as taught by Bolduc, as Bolduc teaches a steerable guide catheter with varying regions of hardness for better control, a bendable curve memory portion and flushing orifices, and further teaches that it is known in the art to position a flushing line about this type of catheter.

In reference to claim 11, Hemmer discloses that the first wall contains a reinforcing structure (116 for example) and the bendable memory portion comprises a memory material (col. 3, lines 43-44).

In reference to claim 12, Hemmer discloses that an inside surface of the first catheter includes a lubricious treatment (60).

In reference to claim 29, Hemmer in view of Bolduc teach that the plurality of orifices would extend through all three layers in order to communicate with the lumen in Fig. 4 of Hemmer.

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In reference to claim 33, Hemmer discloses that the first, second and third layers are concentric (Fig. 4) and the first layer is an inner layer (64 could be interpreted as the first layer and therefore an inner layer), the second layer is a middle layer (116 could be interpreted as the second layer) and the third layer is the outside layer (112 could be interpreted as the outside layer) and the first layer is harder than the second layer (the chart from the website above shows that copper has a higher hardness than steel).

In reference to claim 34, Hemmer discloses that the bendable memory portion comprises nitinol (col. 3, lines 43-44).

In reference to claim 36, Hemmer discloses that the bendable memory portion comprises nitinol (col. 3, lines 43-44) and the bendable memory portion is activated to the second curved configuration by body temperature (col. 5, lines 56-60).

In reference to claim 37, Hemmer discloses that the bendable memory portion is activated to the second curved configuration upon emerging from a second outer catheter (col. 6, lines 19-25).

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hemmer et al. (US Patent No. 5,531,685) in view of Bolduc et al. (US Patent No. 6,622,367) and further in view of Kaldany (US Patent No. 5,222,949). Hemmer in view of Bolduc disclose the device substantially as claimed except for the bendable memory portion comprising a polymer that becomes preformed to a second configuration by exposing it to ultra-violet light. Kaldany, however, discloses a curve memory portion containing a

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cross-linking polymer that when activated by ultraviolet light will become shaped into a predetermined shape (col. 1, lines 34-60). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hemmer in view of Bolduc to include curve memory regions with ultraviolet light activated polymer regions on the second catheter, as taught by Kaldany, in order to provide the second catheter with a flexible structure that can later be hardened into necessary shapes and configurations for the stability of medical tasks and procedures to safely take place.

Allowable Subject Matter

Claims 1, 3, 7, 8, 30-32 are allowed. The following is a statement of reasons for the indication of allowable subject matter: The amendment to independent claim 1 which necessitates the second catheter to have a bendable curve memory portion made from a cross-linking polymer activated by ultraviolet light, was not found.

Response to Arguments

Applicant's arguments with respect to claims 9, 11, 12, 29, 33-37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767